



Patent  
Attorney's Docket No. 032901-101

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of )  
Shigeki OHTA et al. ) Group Art Unit: Unassigned  
Application No.: 10/630,967 ) Examiner: Unassigned  
Filed: July 31, 2003 ) Confirmation No.: Unassigned  
For: METHOD OF ENHANCING NEURAL )  
STEM CELL PROLIFERATION, )  
DIFFERENTIATION, AND SURVIVAL )  
USING PITUITARY ADENYLYATE )  
CYCLASE ACTIVATING  
POLYPEPTIDE (PACAP)

**FIRST  
INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, Applicants hereby submit the following information in conformance with 37 C.F.R. §§ 1.97 and 1.98.

Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited is enclosed.

However, copies of the listed U.S. patent application publications are not enclosed because it is no longer required according to the July 11, 2003 waiver of the requirement for copies of cited U.S. patents and U.S. patent applications in national patent applications filed after June 30, 2003, and international applications entering the national stage under 35 U.S. C. § 371 after June 30, 2003.

The documents are being submitted within three (3) months of the filing or entry of the national stage of this application or before the first Office Action on the merits, whichever is later. Since the documents are being filed within the time period set forth in 37 C.F.R. § 1.97(b) no fee or statement is required.

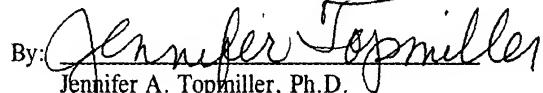
Information Disclosure Statement  
Application No. 10/630,967  
Attorney's Docket No. 032901-101  
Page 2

To assist the Examiner, the documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner-initialed copy of this form be returned to the undersigned.

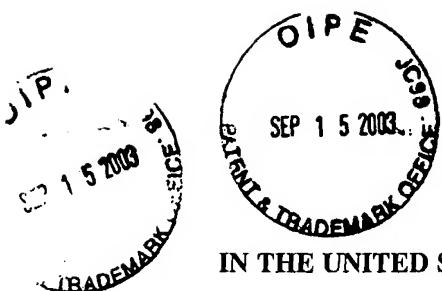
Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: September 15, 2003

By:   
Jennifer A. Topmiller, Ph.D.  
Registration No. 50,435

P.O. Box 1404  
Alexandria, Virginia 22313-1404  
(703) 836-6620



Patent  
Attorney's Docket No. 032901-101

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of )  
Shigeki OHTA et al. ) Group Art Unit: Unassigned  
Application No.: 10/630,967 ) Examiner: Unassigned  
Filed: July 31, 2003 ) Confirmation No.: Unassigned  
For: METHOD OF ENHANCING NEURAL )  
STEM CELL PROLIFERATION, )  
DIFFERENTIATION, AND SURVIVAL )  
USING PITUITARY ADENYLYATE )  
CYCLASE ACTIVATING )  
POLYPEPTIDE (PACAP) )

**INFORMATION DISCLOSURE STATEMENT  
TRANSMITTAL LETTER**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Enclosed is an Information Disclosure Statement and accompanying form PTO-1449 for the above-identified patent application.

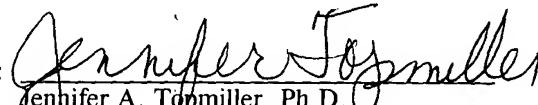
- No additional fee for submission of an IDS is required.  
 The fee of \$180.00 (1806) as set forth in 37 C.F.R. § 1.17(p) is also enclosed.  
 A statement under 37 C.F.R. § 1.97(e) is also enclosed.  
 A statement under 37 C.F.R. § 1.97(e), and the fee of \$180.00 (1806) as set forth in 37 C.F.R. § 1.17(p) are also enclosed.  
 Charge \$\_\_\_\_\_ to Deposit Account No. 02-4800 for the fee due.  
 A check in the amount of \$\_\_\_\_\_ is enclosed for the fee due.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: September 15, 2003

By:   
Jennifer A. Tappmiller, Ph.D.  
Registration No. 50,435

P.O. Box 1404  
Alexandria, Virginia 22313-1404  
(703) 836-6620

31

SEP 15 2003

SHEET 1 OF 3

Substitute for forms 1449A/PTO &amp; 1449B/PTO

ATTORNEY'S DKT No.  
032901-101APPLICATION NO.  
10/630,967

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

APPLICANT  
Shigeki OhtaFILING DATE  
July 31, 2003GROUP  
Unassigned

**U.S. PATENT DOCUMENTS**

Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
	5,128,242		Akira Arimura et al.	07-07-1992
	5,198,542		Haruo Onda et al.	03-30-1993
	5,208,320		Chieko Kitada et al.	05-04-1992
	5,326,860		Haruo Onda et al.	07-05-1994
	5,521,069		Haruo Onda et al.	05-28-1996
	5,547,935		Guy T. Mullenbach et al.	08-20-1996
	5,623,050		Chieko Kitada et al.	04-22-1997
	5,750,376		Samuel Weiss et al.	05-12-1998
	5,801,147		Chieko Kitada et al.	09-01-1998
	5,955,346		James A. Wells et al.	09-21-1999
	6,017,533		Osamu Moro et al.	01-25-2000
	6,165,783		Samuel Weiss et al.	12-26-2000

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Document Number	Kind Code (if known)	Country	Date of Publication (MM-DD-YYYY)	Translation Yes No
	0 456 279 A3		Europe	01-22-1992	
	WO 93/01275		WIPO	01-21-1993	
	WO 94/10292		WIPO	05-11-1994	
	WO 03/040310		WIPO	05-15-2003	

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	A. ARIMURA, "Pituitary Adenylate Cyclase Activating Polypeptide (PACAP):Discovery and Current Status of Research", <i>Regulatory Peptides</i> , 37:287-303 (1992). Elsevier Science Publishers
	A. ARIMURA et al., "Perspectives on Pituitary Adenylate Cyclase Activating Polypeptide (PACAP) in the Neuroendocrine, Endocrine, and Nervous Systems", <i>Jap. J. Physiol.</i> 48:301-331 (1998). Center for Academic Publications, Japan
	A. ARIMURA et al., "Tissue Distribution of PACAP as Determined by RIA: Highly Abundant in the Rat Brain Testes", <i>Endocrinol.</i> 129:2787-2789 (1991). Williams & Wilkins
	A. ARIMURA et al., "PACAP Functions as a Neurotrophic Factor", <i>Ann. N.Y. Acad. Sci.</i> 739:228-243 (1994). New York Academy of Science, New York
	W.A. BANKS et al., "Passage of Pituitary Adenylate Cyclase Activating Polypeptide 1-27 and Pituitary Adenylate Cyclase...", <i>J. Pharmacol. Exp. Ther.</i> 267(2):690-6 (1993). William & Wilkins
	S.A. BAYER, "Neuron Production in the Hippocampus and Olfactory Bulb of the Adult Rat Brain: Addition or Replacement?", <i>N.Y. Acad. Sci.</i> 457:163-173 (1985). New York Academy of Sciences, New York

Examiner Signature	Date Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



SHEET 2 OF 3

Substitute for forms 1449A/PTO &amp; 1449B/PTO

ATTORNEY'S DKT NO.  
032901-101APPLICATION NO.  
10/630,967INFORMATION DISCLOSURE  
STATEMENT BY APPLICANTAPPLICANT  
Shigeki Ohta  
FILING DATE  
July 31, 2003GROUP  
Unassigned

## U.S. PATENT DOCUMENTS

Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
	6,191,106		Guy T. Mullenbach et al.	02-20-2001
	6,242,563		Zheng Xin Dong	06-05-2001
	6,294,346		Samuel Weiss et al.	09-25-2001
	6,399,316		Haruo Onda et al.	06-04-2002
	6,429,186		Germaine Fuh et al.	08-06-2002

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Document Number	Kind Code (if known)	Country	Date of Publication (MM-DD-YYYY)	Translation Yes No

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	S. BERNICHEIT et al., "S179D-human PRL, a Pseudophosphorylated Human PRL Analog, is an Agonist and not an Antagonist", Endocrinology 142(9):3950-3963 (2001). The Endocrine Society
	R.G. CAREY et al., "Pituitary Adenylate Cyclase Activating Polypeptide Antimitogenic Signaling in Cerebral Cortical Progenitors is Regulated by p57Kip2-dependent CDK2 activity," J. Neurosci. 22(5):1583-91 (2002). Society for Neuroscience
	J. CHRISTOPHE, "Type I Receptors for PACAP (a neuropeptide even more important than VIP?)" Biochim. Biophys. Acta 1154:183-99 (1993). Elsevier Science Publishers
	C.G. CRAIG et al., "In vivo Growth Factor Expansion of Endogenous Subependymal Neural Precursor Cell Populations in Adult Mouse Brain," J. Neurosci. 16(8):2649-58 (1996) Society for Neuroscience
	C.R. FREED et al., "Survival of Implanted Fetal Dopamine Cells and Neurologic Improvement 12 to 46 Months After Transplantation for Parkinson's Disease", N. Engl. J. Med. 327:1549-1555 (1992).
	D.E. HANSEL et al., "Regulation of Olfactory Neurogenesis by Amidated Neuropeptides," J. Neurosci. Res. 66:1-7 (2001). Wiley-Liss
	H. HASHIMOTO et al., "Altered Psychomotor Behaviors in Mice Lacking Pituitary Adenylate Cyclase-Activating Polypeptide (PACAP)", PNAS 98:(23)13355-13360 (2001)
	H. HASHIMOTO et al., "Molecular Cloning and Tissue Distribution of a Receptor for Pituitary Adenylate Cyclase Activating Polypeptide", Neuron 11:333-342 (1993). Cell Press
	M.S. KAPLAN, "Neurogenesis in the 3-month Old Rat Visual Cortex," J. Comp. Neurol. 195:323-338 (1981). Alan R. Liss
	C. KIMURA et al., "A Novel Peptide Which Stimulates Adenylate Cyclase: Molecular Cloning and Characterization of the Ovine and Human cDNAs," Biochem. Biophys. Res. Comm. 166:81-89 (1990). Academic Press
	D. VAN DER KOY and S. WEISS, "Why Stem Cells?", Science 287:1439-41 (2000).
	D. LINDHOLM et al., "Developmental Regulation of Pituitary Adenylate Cyclase Activating Polypeptide (PACAP) and its Receptor 1 in Rat Brain: Function of PACAP as a Neurotrophic Factor," Ann. N.Y. Acad. Sci. 865:189-96 (1998). New York Acad. Sciences, New York
	N. LU et al., "Pituitary Adenylate Cyclase-Activating Polypeptide is an Autocrine Inhibitor of Mitosis in cultured Cortical Precursor Cells," Proc. Natl. Acad. Sci. USA 94:3357-3362 (1997). The Natl. Acad. of Sciences of the USA
	A. MIYATA et al., "Isolation of a Novel 38 Residue-Hypothalamic Polypeptide which Stimulates Adenylate Cyclase in Pituitary Cells," Biochem. Biophys. Res. Comm. 164:567-574 (1989). Academic Press

Examiner Signature	Date Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for forms 1449A/PTO & 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		ATTORNEY'S DKT NO. 032901-101	APPLICATION NO. 10/630,967
		APPLICANT Shigeki Ohta	
		FILING DATE July 31, 2003	GROUP Unassigned



<b>U.S. PATENT DOCUMENTS</b>				
Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)

<b>FOREIGN PATENT DOCUMENTS</b>					
Examiner Initials	Document Number	Kind Code (if known)	Country	Date of Publication (MM-DD-YYYY)	Translation Yes No

<b>NON PATENT LITERATURE DOCUMENTS</b>	
Examiner Initials	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	A. NICOT et al., "Regulation of Neuroblast Mitosis is Determined by PACAP Receptor Isoform Expression", PNAS 98(8)4758-4763 (2001).
	C. OTTO et al., "Altered Emotional Behavior in PACAP-type-I-receptor-deficient Mice," Brain Res. Mol. Brain Res. 91(1-2):78-84 (2001). Elsevier Science
	M.J. PERLOW et al., "Brain Grafts Reduce Motor Abnormalities Produced by Destruction of Nigrostriatal Dopamine System," Science 204:643-647 (1979). Amer. Acad. for the Advancement of Science
	C.S. POTEN and LOEFFLER, "Stem Cells: Attributes, Cycles, Spirals, Pitfalls and Uncertainties. Lessons for and from the Crypt," Development 110:1001-1020 (1990). Company of Biologists, Ltd.
	P. RAKIC, "Limits of Neurogenesis in Primates," Science 227:1054-1056 (1985).
	S.R. RAWLINGS, "At the Cutting Edge PACAP, PACAP Receptors, and Intracellular Signalling", Mol. and Cellular Endocrinol. 191:C5-C9 (1994). Elsevier Science Ireland Ltd.
	B.A. REYNOLDS and S. WEISS, "Generation of Neurons and Astrocytes from Isolated Cells of the Adult Mammalian Central Nervous System," Science 255:1701-1710 (1992).
	R. RIETZE et al., "Mitotically Active Cells that Generate Neurons and Astrocytes are Present in Multiple Regions of the Adult Mouse Hippocampus," J. Comp. Neurol. 424(3):397-408 (2000). Wiley-Liss
	T. SHINGO et al., "Erythropoietin Regulates the <i>in vitro</i> and <i>in vivo</i> Production of Neuronal Progenitors by Mammalian Forebrain Neural Stem Cells," J. Neurosci. 21(24):9733-9743 (2001). Society for Neuroscience
	D.D. SPENCER et al., "Unilateral Transplantation of Human Fetal Mesencephalic Tissue into the Caudate Nucleus of Patients with Parkinson's Disease," New Engl. J. Med. 327:1541-1548 (1992). Massachusetts Medical Society
	D. VAUDRY et al., "Pituitary Adenylate Cyclase-Activating Polypeptide and Its Receptors from Structure to Functions," Pharmacol. Rev. 52:269-324 (2000). The Amer. Soc. for Pharmacol. & Exp. Ther.
	J.A. WASCHEK, "VIP and PACAP Receptor-mediated Actions on Cell Proliferation and Survival," Ann. N.Y. Acad. Sci. 805:290-300 (1996). New York Academy of Sciences, New York
	H. WIDNER et al., "Bilateral fetal Mesencephalic Grafting into Two Patients with Parkinsonism induced by 1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine (MPTP)," N. Engl. J. Med. 327:1556-1563 (1992). Massachusetts Medical Society
	A. YUHARA et al., "PACAP has a Neurotrophic Effect on Cultured Basal Forebrain Cholinergic Neurons from Adult Rats," Brain Res. Dev. Brain Res. 131(1):41-5 (2001). Elsevier Science

Examiner Signature	Date Considered
--------------------	-----------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.